



# IUCLID

for pesticides

---

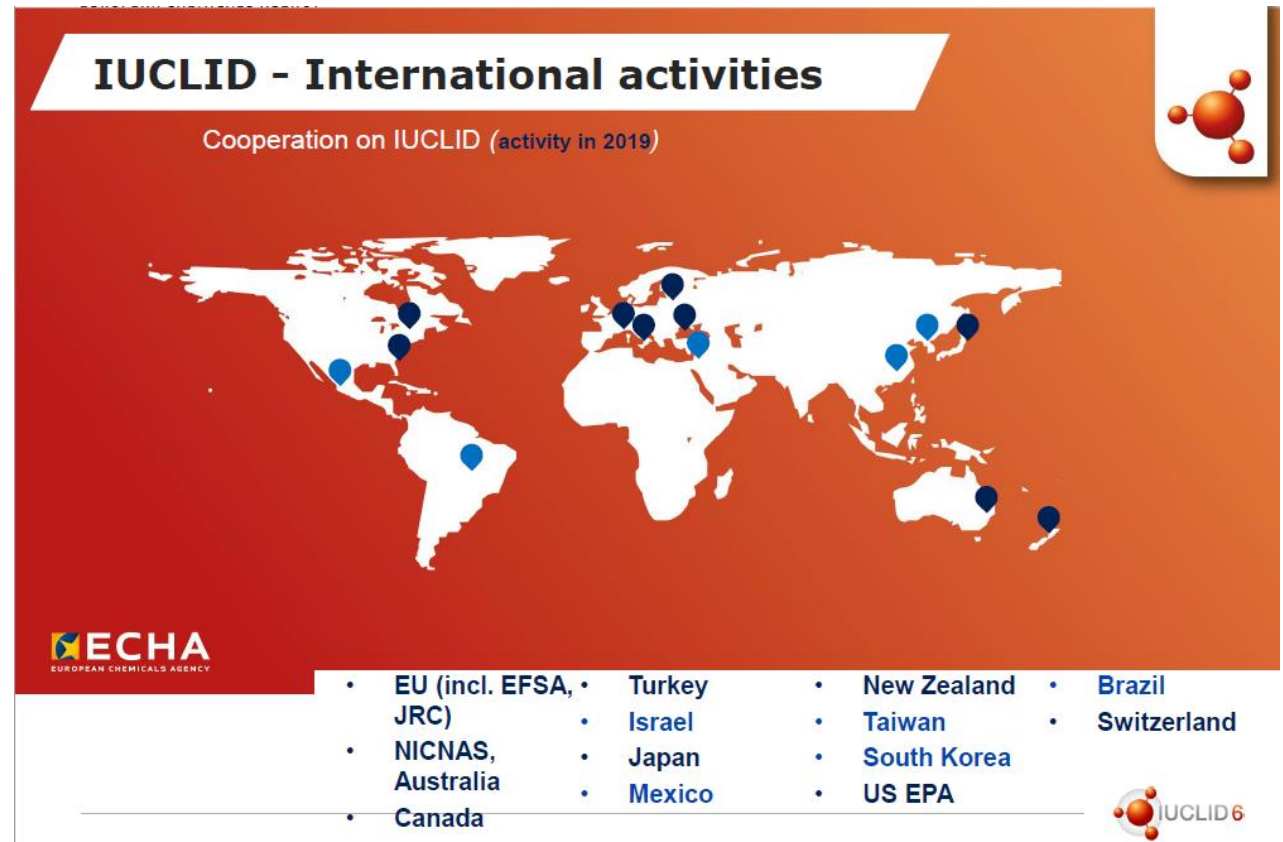
**WHY IT WAS IMPLEMENTED AND HOW IT WILL  
BE USED**

ABIM 20<sup>TH</sup> OCTOBER 2020

MARC TEIWES, BASF SE

# IUCLID (International Uniform Chemical Information database)

- ❖ IUCLID was implemented in 1993 as a software application to capture, store, maintain and exchange data on intrinsic and hazard properties on chemical substances
- ❖ Hosted by ECHA (European Chemicals Agency) in collaboration with OECD



Source: ECHA

# IUCLID – key drivers

---

## **EFSA Matrix project**

- Transparent evidence management and **structured data** to support the scientific assessment

## **One substance – one hazard assessment**

- Alignment of REACH, CLP and agrochemical assessment

## **Transparency Regulation**

- Amendment of article 39f of General Foodlaw calling EFSA to define standard data formats

# IUCLID implementation milestones

---

 **European Chemicals Agency**  
4h

Together with **European Food Safety Authority (EFSA)**'s management team, we signed an agreement for using #IUCLID also for data related to #pesticides. We discussed further cooperation to improve risk assessment and research on chemical #substances. #SaferChemicals



42 Likes

 Like  Comment  Share



---

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

**EFSA Technical Group on PESTICIDES – IUCLID pilot**

# IUCLID Pilot (and beyond)

---

- ❖ Started in November 2019 commenced in April 2020
- ❖ Technical Working Group still active today
- ❖ Participants from all stakeholders:
  - Applicants: IBMA, ECPA, ECCA
  - Competent MS authorities: France, Germany, Finland, Portugal, Austria
  - EFSA
  - COM
- ❖ POC Dossiers for chemical active substance and microorganism (353 issues identified)
- ❖ Continuous work on improving the system (e.G. 16 endpoint study records change requests for microorganisms)
- ❖ Currently ongoing: Testing of IUCLID 6.5



# IUCLID legal implementation

---

- ❖ For renewals: Draft Renewal Regulation for voting in October 22/23 ScoPAFF containing article 7 for mandatory IUCLID submission
- ❖ For new approvals: First discussion in ScoPAFF
- ❖ For MRLs: ?
- ❖ For national product authorisations: IUCLID not foreseen at this stage

## *Article 7*

### **Format and software for the submission of the application for renewal**

- . The Authority shall establish and make available online a central submission system. The Authority shall ensure that the central submission system facilitates the verification of admissibility performed by Member States in accordance with Article 8.
- . The standard data formats proposed by the Authority as part of the IUCLID software package pursuant to Article 39f of Regulation (EC) No 178/2002 are hereby adopted.
- . The application for renewal shall be submitted via the central submission system using the IUCLID software package.
- . The applicant, when requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, shall indicate such information using the relevant IUCLID functionality.

# IUCLID general setup

---

IUCLID consists of data for substances and mixtures linked to a Legal entity

All data objects can be uniquely identified by a UUID

Data can be sorted according to different legislations by Working context

Working context:

**EU PPP Microorganisms - active substance information**

- 1. Identity of the microorganism and applicant 1
- 2. Biological properties of the microorganism
- 3. Further information on the microorganism
- 4. Analytical methods 2
- 5. Effects on human health
- 6. Residues in or on treated articles, food and feed 6

### Substance information

[View Dossiers](#)

Substance name	Test substance_2020_10_07		
IUPAC name			
Legal entity	(EFSA Pilot) ECPA, Industry	UUID	594ef285-bc3d-4676-87e5-c0e3a20ab9e5
CAS number		EC number	

[Templates](#) ▼

▼ 1 Identity of the microorganism and applicant 1

# IUCLID general setup

---

Data can be entered into:

- Endpoint summary documents
- Study summary documents (OECD Harmonised Templates),
- Domain specific documents

for the substance (microorganism) and the mixture

The screenshot displays the IUCLID interface for a substance entry. At the top, there are two 'None' labels with icons. Below them is a text input field containing 'Good Agricultural Practices (GAP).001'. Underneath the input field is the UUID: 'eb0601b9-afca-4c76-becb-d37e904f87cf'. The 'Administrative data' section shows two 'None' labels with icons. Below this is a 'Product' dropdown menu with a question mark icon and a downward arrow. The selected product is 'Detailed quantitative and qualitative information on the composition of the plant protection pr', with a close button (X) on the right. The 'Description of key information' section shows 'None'. Below this is the 'Crop information' section, which includes a 'Crop / treated object' label and a list of three checked items: '1ZANG Zanthoxylum - 0820020 (crops > 1ZANG Zanthoxylum - 0820020)', '3CERC (Cereal crops) (crops > 3CERC (Cereal crops))', and '3DWHC (Durum wheat crops) (crops > 3DWHC (Durum wheat crops))'.

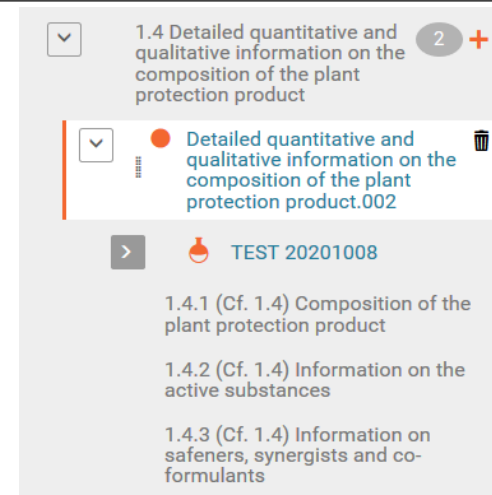


# IUCLID Dossier compilation

All components of the assessment entity need to be linked within the mixture (representative product)


Dossier representing a snapshot of the relevant data at a time

Dossier will have to be compiled from the representative product and submitted to EFSA instance of ECHA Cloud



1.4 Detailed quantitative and qualitative information on the composition of the plant protection product 2 +

- ▼ Detailed quantitative and qualitative information on the composition of the plant protection product.002 🗑️
- ▶️ 🔥 TEST 20201008
  - 1.4.1 (Cf. 1.4) Composition of the plant protection product
  - 1.4.2 (Cf. 1.4) Information on the active substances
  - 1.4.3 (Cf. 1.4) Information on safeners, synergists and co-formulants



← EU PPP Active substance application (product)

**Dossier name (given by user)**  
None

**Dossier submission remark**  
None

**Active substance approval**

**European reference number**  
None

**Purpose of the application**  
None

**Rapporteur Member State (RMS)**  
None

**Competent authority**  
None

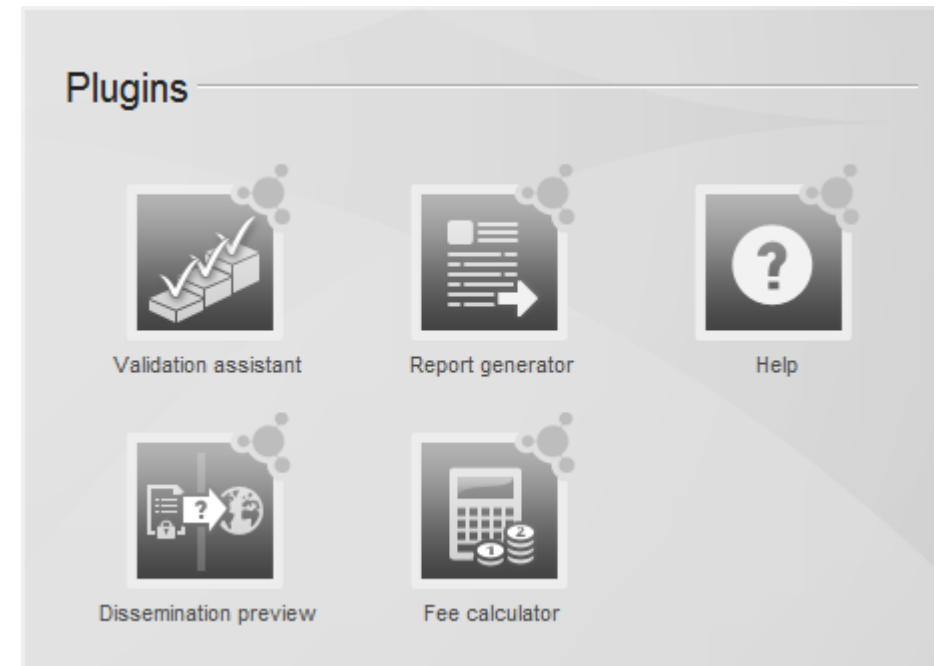
**Co-RMS**  
None

# IUCLID Evaluation process

---

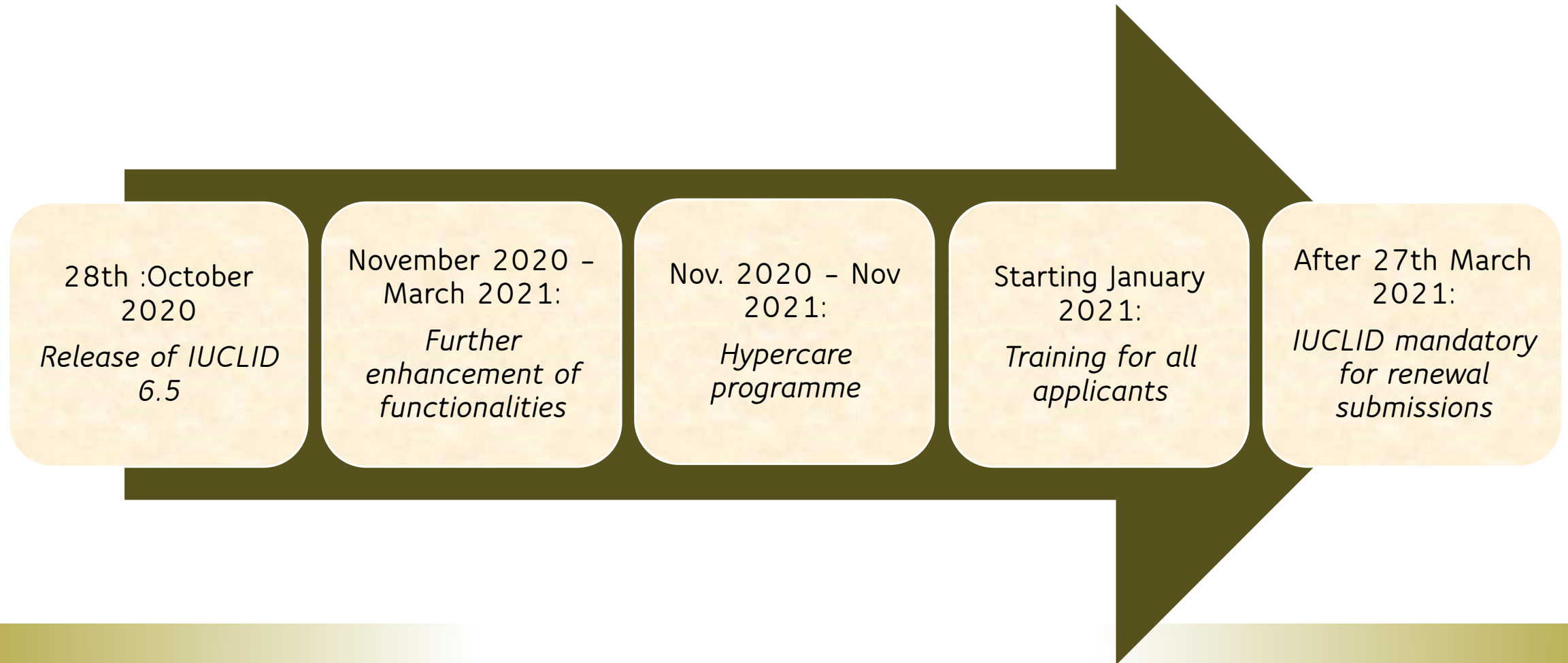
Several features implemented or to be implemented to support the evaluation process:

- Validation rules to perform a Completeness Check
- Annotations to be used for communication between evaluator and applicant
- Reporting functionalities for automation of LOEP, Reference Lists, DAR or RAR (future Vision)
- Dissemination tool for publication



# IUCLID implementation steps

---



# IUCLID challenges for applicants

---

- ❖ Insufficient OHTs (designed for chemical evaluation)
- ❖ Missing OHTs and documents (for higher tier studies, Risk assessments etc. )
- Traditional summary Dossier (Document M) still required to ease evaluation process
  - Significant increase of workload for applicants
  - Significant change management needed for Dossier generation process
  - Further Delays in the evaluation process can be expected

!Even more severe for microorganisms!

Thank You

---

Time for Questions ?